

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SANOFI-AVENTIS DEUTSCHLAND
GMBH, AVENTIS PHARMA S.A.,
ABBOTT GMBH & CO. KG and
ABBOTT LABORATORIES

Plaintiff,

v.

GLENMARK PHARMACEUTICALS
INC., USA and GLENMARK
PHARMACEUTICALS LTD,

Defendants.

Hon. Dennis M. Cavanaugh

OPINION

Civil Action No. 07-CV-5855 (DMC-JAD)

DENNIS M. CAVANAUGH, U.S.D.J.

This matter comes before the Court upon motion by Defendants Glenmark Pharmaceuticals, Inc., USA and Glenmark Pharmaceuticals, Ltd. (collectively, “Defendants”) to dismiss Abbott Laboratories (“Abbott Laboratories”) and Abbott Laboratories, Inc. (“ALI”) (collectively, “Plaintiffs”) pursuant to Fed. R. Civ. P. 12(b)(1). Defendants also move for summary judgment pursuant to Fed. R. Civ. P. 56 that Abbott GmBH & Co. KG, Abbott Laboratories, and ALI are not entitled to lost profits. Pursuant to Fed. R. Civ. P. 78, no oral argument was heard. After considering the submissions of all parties, it is the decision of this Court for the reasons herein expressed that Defendants’ motions are **denied**.

I. BACKGROUND¹

The '244 patent, titled "Combination of Angiotensin-Converting Enzyme Inhibitors with Calcium Antagonists as well as their Use in Drugs[,]" issued on February 24, 1998, with a filing date of June 7, 1995 and a foreign application priority date of October 2, 1986. The '244 patent discloses and claims a "pharmaceutical composition" used to treat hypertension. The pharmaceutical composition contains an angiotensin-converting enzyme inhibitor ("ACE inhibitor") having certain bicyclic or tricyclic ring systems and a calcium antagonist (also known as a calcium channel blocker or "CCB") in "amounts effective for treating hypertension."

The '244 patent issued on February 24, 1998 to inventors Reinhard Becker, et al. The patent was initially assigned to Hoechst Aktiengesellschaft who subsequently assigned ownership rights to Aventis Pharma Deutschland GmbH, renamed Sanofi-Aventis Deutschland GmbH. Aventis Pharma S.A. was granted an exclusive license to manufacture, use and sell pharmaceutical products containingtrandolapril and verapamil hydrochloride. Aventis Pharma S.A. granted Abbott Germany an exclusive license to manufacture, use and sell pharmaceutical products containingtrandolapril and verapamil hydrochloride. Abbott Germany in turn granted Abbott Laboratories an exclusive license to manufacture, use and sell pharmaceutical products containingtrandolapril and verapamil hydrochloride. Abbott Laboratories granted ALI an exclusive sublicense to use and sell pharmaceutical products containingtrandolapril and verapamil.

Abbott Laboratories is the owner of the New Drug Application ("NDA") No. 20-591. Pursuant to the NDA approval, Abbott Laboratories, through ALI, sells drug products containing thetrandolapril/verapamil hydrochloride combination in the United States under the trademark Tarka®.

¹ The facts set-forth in this Opinion are taken from the Parties' statements in their respective moving papers.

The ‘244 patent is listed in FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluation” (“Orange Book”) as being applicable to Abbott Laboratories’ aforementioned NDA for its Tarka® tablets.

On July 24, 2007, Glenmark filed an Abbreviated New Drug Application (“ANDA”) No. 79-135 with the FDA for approval to market a generic version of the drug Tarka®. On October 24, 2007, Glenmark notified Plaintiffs that it had made a “Paragraph IV” certification asserting that the ‘244 patent is invalid. On December 7, 2007, consistent with the provisions of the Hatch-Waxman Act, Plaintiffs initiated suit before this Court against Defendants for patent infringement.

II. MOTION TO DISMISS

A. LEGAL STANDARD

1. Standard of Review for Motion to Dismiss Pursuant to Rule 12(b)(1)

Standing is a threshold requirement in any federal lawsuit, and the party must have standing at the time it brings the suit. Sicom Sys., Ltd. V. Agilent Techs., Inc., 427 F.3d 971, 975-76 (Fed. Cir. 2005). “The party bringing the action bears the burden of establishing that it has standing.” Id. at 976. The district court must accept the complaint’s allegations as true and ““general factual allegations of injury resulting from the defendant’s conduct may suffice, for on a motion to dismiss [it is] presume[d] that general allegations embrace those specific facts that are necessary to support the claim.”” Wiav Solutions LLC v. Motorola, Inc., 631 F.3d 1257, 1264 (Fed. Cir. Dec. 22, 2010) (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992)). However, “consideration of a Rule 12(b)(1) jurisdiction-type motion need not be limited; conflicting written and oral evidence may be considered and a court may ‘decide for itself the factual issues which determine jurisdiction.’” Id. (citing Williamson v. Tucker, 645 F.2d 404, 413 (5th Cir.) Cert. denied, 454 U.S.

897 (1981)). “When resolving a factual challenge, the court may consult materials outside the pleadings, and the burden of proving jurisdiction rests with the plaintiff.” Med. Soc’y of N.J. v. Herr, 191 F. Supp. 2d 574, 578 (D.N.J. 2002) (citing Gould Elecs. Inc. v. U.S., 220 F.3d 169, 176, 178 (3d Cir. 2000)).

2. Standing in a Patent Case

“[T]he touchstone of constitutional standing in a patent infringement suit is whether a party can establish that it has an exclusionary right in a patent that, if violated by another, would cause the party holding the exclusionary right to suffer legal injury.” Wiav Solutions, 631 F.3d at 1265. “Only a patent owner or an exclusive licensee can have constitutional standing to bring an infringement suit; a non-exclusive licensee does not.” Mars, Inc. v. Coin Acceptors, Inc., 527 F.3d 1359, 1367 -1368 (Fed. Cir. 2008).

“To be an exclusive licensee for standing purposes, a party must have received, not only the right to practice the invention within a given territory, but also the patentee's express *or implied* promise that others shall be excluded from practicing the invention within that territory as well.” Rite-Hite Corp. V. Kelley Co., Inc., 56 F.3d 1538,1552 (Fed. Cir. 1995)(emphasis added). Since exclusive licenses can be implied, “an exclusive license *need not be in writing* for the exclusive licensee to have standing to sue with the patentee as a co-plaintiff.” Aspex Eyewear, Inc. v. Altair Eyewear, Inc., 288 Fed. Appx. 697, 705 (Fed. Cir. 2008) (emphasis added).

“The proprietary rights granted by any patent are the rights to exclude others from making, using or selling the invention in the United States.” Ortho Pharm. Corp. v. Genetics

Institute, Inc., 52 F.3d 1026, 1031-32 (Fed. Cir. 1995). An exclusive license “transfer[s] some of those proprietary rights from the patentee to its licensee... [and] makes the licensee a beneficial owner of some identifiable part of the patentee's bundle of rights to exclude others.” Id. “[A] licensee is an exclusive licensee of a patent if it holds *any* of the exclusionary rights that accompany a patent.” Wiav Solutions, 631 F.3d at 1266 (emphasis added); see also Amgen, Inc. V. Chugai Pharm. Co., 808 F. Supp. 894, 900 (D. Mass. 1992) (citing Weinar v. Rollform, Inc., 744 F.2d 797 (Fed. Cir. 1984)) (“A licensee can be deemed exclusive where the license pertains to less than all three of the rights granted under the patent, such as where the licensee has obtained only the exclusive right to sell the patented invention.”). “[I]t is the licensee's beneficial ownership of a right to prevent others from making, using *or* selling the patented technology that provides the foundation for co-plaintiff standing, not simply that the word ‘exclusive’ may or may not appear in the license.” Id. at 1032 (emphasis added).

“If the party has not received an express or implied promise of exclusivity under the patent, i.e., the right to exclude others from making, using, or selling the patented invention, the party has a ‘bare license,’ and has received only the patentee's promise that that party will not be sued for infringement.” Rite-Hite, 56 F.3d at 1552; see also Mars, Inc., 527 F.3d at 1368 (“By the same token, if the patentee *allows* others to practice the patent in the licensee's territory, then the licensee is *not* an exclusive licensee.”). “The grant of a bare license to sell an invention in a specified territory, even if it is the only license granted by the patentee, does not provide standing without the grant of a right to exclude others.” Rite-Hite, 56 F.3d at 1552; see also Sicom, 427 F.3d at 976 (“A nonexclusive license confers no constitutional standing on the licensee to bring suit or even to join a suit with the patentee because a nonexclusive licensee suffers no legal

injury from infringement.”).

B. DISCUSSION

Defendants argue that Abbott Laboratories and ALI lack standing because they are not the exclusive licensees of the patent in suit.

In support of their argument, Defendants largely rely on the lack of any documentary evidence explicitly stating Abbott Laboratories and ALI were the exclusive licensees of the ‘244 Patent. However, by over emphasizing the lack of documentary evidence evincing an exclusive licensee agreement between Abbott Germany and Abbott Laboratories and ALI, Defendants ignore the fact that exclusive licenses can be *implied*. This Court agrees with Defendants that the promise of an exclusive license cannot be implied merely based on corporate structure. As Defendants correctly point out, “the fact that a corporate party is affiliated with or in a parent-subsidary relationship with the patent owner or exclusive licensee is not sufficient to confer standing.” This Court agrees with Defendants that if the only evidence supporting Plaintiffs’ claim of an implied exclusive license was the corporate relationships among the Abbott entities, then Plaintiffs’ claim would necessarily fail. However, here, Plaintiffs have provided sufficient evidence for this Court to conclude that Plaintiffs are exclusive licensees, and therefore this Court finds Plaintiffs have standing.

Plaintiffs argue that they have an implied exclusive license because they have the exclusive right to market and sell the patented product in the United States.² Plaintiffs trace the

²Plaintiffs also state that the exclusive license was memorialized in a Confirmatory Exclusive License Agreement (“2010 Confirmatory Agreement”), which was signed by Abbott Germany, Abbott Laboratories, and ALI. Defendants argue that the 2010 Confirmatory Agreement is void for lack of consideration since the parties were already obligated to make reasonable efforts to sell the patented product by virtue of the Exclusive Distributor Agreements

exclusive license to 2001 when Abbott Germany acquired Knoll, a German pharmaceutical company, and through that acquisition acquired the exclusive rights to develop, register, formulate and sell trandolapril-verapamil combinations in the United States. Abbott Germany then designated Abbott Laboratories as the sole owner of the New Drug Application (“NDA”),³ which made Abbott Laboratories the sole owner of the right to sell the trandolapril-verapamil combination in the United States. Abbott Laboratories’ exclusive rights include all of Abbott Germany’s field of use, namely trandolapril-verapamil combinations, but are limited to the rights to market and sell. ALI became a sublicensee based on the distributor agreements between Abbott Laboratories and ALI, which provided ALI with the exclusive right to sell trandolapril-verapamil combinations on behalf of Abbott Laboratories in the United States. These rights were continued in the 2004 Agreement, wherein Abbott Germany acquired an exclusive license to the ‘244 Patent. Based on the 2004 Agreement, Abbott Germany had the exclusive license to manufacture, use, and sell TARKA, and was able to sublicense those rights. The 2004 Agreement did not extinguish the preexisting rights of Abbott Laboratories and ALI with regard

between Abbott Laboratories and ALI. Plaintiffs contend that since the 2010 Confirmatory Agreement merely recites the existing exclusive licensing arrangements and, therefore, is not a new contract or contract modification no consideration is required. Alternatively, Plaintiffs argue that if the parties had not already entered these exclusive licensing arrangements, the 2010 Confirmatory Agreement creates new rights and obligations and Defendants have failed to show that no new consideration has been exchanged between the parties. Since this Court finds that the Plaintiffs had an implied exclusive license to sell the patented product in the United States, the Court need not address the arguments regarding the 2010 Confirmatory Agreement.

³While Defendants are correct in asserting that Plaintiffs’ NDA is not in itself a patent license, it would be incorrect to assume it has no bearing on whether or not an exclusive license exists. In fact, Abbott Germany’s designation of Abbott Laboratories as the sole owner of the NDA provides circumstantial evidence of Abbott Germany’s implied promise to exclude others from selling and distributing the patented product.

to their exclusive rights to sell TARKA in the United States.

Although these agreements do not explicitly state “Abbott Laboratories and ALI are exclusive licensees of the ‘244 patent,” no such explicit written agreement is required to confer an exclusive license. When the 2001 acquisition of the NDA, the exclusive distributor agreement, and the 2004 agreement are considered together, they indicate intent of the parties to provide Abbott Labs and ALI with an exclusive license.

Based on the foregoing, this Court finds that Plaintiffs were an exclusive licensee because it had the right to market and sell the patented product in the United States to the exclusion of others. As discussed above, the exclusive license need not be in writing and can be implied. Here, the promise was implied. Through the implied promise, Plaintiffs did not receive a “bare license,” but rather became the “beneficial owner[s] of some identifiable part of the patentee’s bundle of rights to exclude others,” namely the right to exclude others from marketing and selling the patented product in the United States. As exclusive licensees, Plaintiffs suffer injury from infringement and therefore have standing in this suit. Accordingly, Defendants motion to dismiss for lack of standing is **denied**.

III. MOTION FOR SUMMARY JUDGMENT

A. LEGAL STANDARD

Summary judgment is granted only if all probative materials of record, viewed with all inferences in favor of the non-moving party, demonstrate that there is no genuine issue of material fact and that the movant is entitled to judgment as a matter of law. See FED. R. CIV. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 330 (1986). “A party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion.” See Celotex

Corp., 477 U.S. at 323. “This burden has two distinct components: an initial burden of production, which shifts to the nonmoving party if satisfied by the moving party; and an ultimate burden of persuasion, which always remains on the moving party.” Id. at 330.

“In determining whether there are any issues of material fact, the Court must resolve all doubts as to the existence of a material fact against the moving party and draw all reasonable inferences - including issues of credibility - in favor of the nonmoving party.” Newsome v. Admin. Office of the Courts of the State of N.J., 103 F. Supp.2d 807, 815 (D.N.J. 2000), aff’d, 51 Fed. Appx. 76 (3d Cir. 2002) (citing Watts v. Univ. of Del., 622 F.2d 47, 50 (D.N.J. 1980)).

While a court must draw reasonable inferences, the non-moving party “may not rest upon the mere allegations or denials of his pleading” to satisfy this burden, but must produce sufficient evidence to support a jury verdict in his favor. See FED. R. CIV. P. 56(e); see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). “The mere existence of a scintilla of evidence in support of the [non-moving party]’s position will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmovant].” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986). Additionally, “unsupported allegations in memorandum and pleadings are insufficient to repel summary judgment.” Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990). Likewise, conclusory allegations are insufficient to establish genuine issues of fact. Lujan v. Nat’l Wildlife Fed’n, 497 U.S. 871, 902 (1990). The non-moving party “must do more than simply show that there is some metaphysical doubt as to the material facts.” Matsushita Elec. Indus. Co., 475 U.S. at 586.

B. DISCUSSION

Defendants argue that Plaintiffs should not be allowed to argue for lost profits based on a payment between co-Plaintiffs Sanofi Aventis and Abbott. Under the 2004 Licensing Agreement (“Agreement”) for manufacturing rights to the patent, Abbott paid \$290 million in up front payments to Aventis. Of that amount, approximately \$150 was credited to exclusive license to the patent-in-suit. The Agreement provided for a price reduction from the up front payments based on the date a generic product enters the market place. Since the price reduction for 2010 is greater than the estimated lost profit damages, Defendants argue the payment from Aventis to Abbott offsets any lost profit damages suffered by Plaintiffs.

The instant argument was also the subject of one of Plaintiffs’ motions in limine (motion in limine #4) wherein Plaintiffs sought to exclude any testimony relating to the payment between Aventis and Abbott. This Court agreed with Plaintiffs that under the collateral source rule the payment between the Plaintiffs did not offset any damages from lost profits. Accordingly, this Court granted Plaintiffs’ motion in limine to exclude any testimony related to the payment. Given that this Court previously determined that the payment could not offset the lost profits damages, Defendants argument that Plaintiffs cannot recover lost profits as a matter of law must necessarily fail. Accordingly, Defendants’ motion for summary judgment must be denied.

IV. CONCLUSION

For the foregoing reasons, Defendants’ motions are **denied**.

Dated: June 30, 2011
 cc: All Counsel of Record
 Hon. J. A. Dickson, U.S.M.J.
 File

S/ Dennis M. Cavanaugh
 Dennis M. Cavanaugh, U.S.D.J.